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K011435
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SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Urinary Incontinence Treatment System, Models HMT21 and HMT2000

June 15, 2000

A. General Provisions

Submitter's Name:	HMT, Inc.
Submitter's Address:	3/4FL. Hak Bldg., 249-13, Yangjae-Dong, Seocho-Gu, Seoul, Korea 137-130
Contact Person:	Seung Kee Mo/President HMT, Inc. TEL:+82-2-3461-7235 FAX:+82-2-3461-7238
Official Correspondent:	Jay Uhm/COO HMT-USA, Inc 26676 Brandon Mission Viejo, CA 92692 TEL:(949)348-1047 FAX : 949-348-1056
Classification Name:	Non-implanted Electrical Continence Device 21 CFR 876.5320, 78KPI, Class II
Proprietary Name:	Kontinence HMT21 and Kontinence HMT2000
Common Name:	Urinary Incontinence Treatment System

B. Name of Predicate Devices

- Empi, Inc. Innosense Pelvic Floor Stimulation and Electromyography System, K971527
- Hollister, Inc. PRS9300 Pelvic Floor Therapy System, K974048

C. Device Description

The Kontinence HMT21 and Kontinence HMT2000 consist of the electrostimulation unit and the applicators that electrical stimulation to a patient in order to help train neuromuscular tissue in the pelvic floor, and that detect biofeedback from a patient in order to monitor the pelvic muscle activity which is otherwise difficult due to the anatomical location of the pelvic floor muscles, for improvement or restoration of urinary continence for women. The applicator includes a pressure transducer that provides biofeedback relating to the contractions of the pelvic floor muscles. The electrical

stimulation energy and power for the transducer are conducted to the applicators and the electrodes.

The HMT21 is battery-powered device and the HMT2000 is AC-powered with a personal computer.

D. **Indication for Use**

Kontinence devices are indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control:

- Improvement of urethral sphincter closure (stress incontinence)
- Strengthening of pelvic floor muscles (stress incontinence)
- Inhibition of the detruser (bladder) muscle through reflexive mechanisms (urge incontinence0
- Neuromuscular Reduction
- Fecal Incontinence (EMG use only)

Models HMT21 and HMT2000 are also indicated during incontinence treatment for assessing EMG activity (in HMT21 and HMT2000) or Pressure (in HMT2000 only) of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

E. **Statement of Technological Characteristics of the Devices**

The proposed devices are substantially equivalent to the predicated devices. The following is a chart comparing the deveces

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

HMT, Inc.
c/o Mr. Charlie Mack
Senior Project Engineer
Conformity Assessment Services
Underwriters Laboratories, Inc.®
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K011435
HMT 21 and HMT 2000 Urinary Incontinence Devices
Dated: May 31, 2001
Received: June 7, 2001
Regulatory Class: II
21 CFR §876.5320/Procode: 78 KPI

Dear Mr. Mack:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number: (if known): K011435

Device Name: Kontinence HMT21 and Kontinence HMT2000 Urinary Incontinence Treatment System

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011435

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109)